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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) 5)	☐ Interview Summary (PTO-413) Paper No(s)/Mail Date ☐ Notice of Informal Patent Application	

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DETAILED ACTION

The previous Action (paper number 20100120) mailed on 03 February 2010 is vacated. A new period for response starts from the mailing date of this action (paper number 20100426).

Claim Status

Claims 1-14 are pending.

Claims 1-14 have been examined.

Claims 1-14 are rejected.

Election/Restrictions

The restriction requirement is withdrawn. The invention of Group I, claims 1-5 is rejoined with the invention of Group II, Claims 6-14.

Priority

This application was filed on 21 September 2006 and is the 35 USC 371 National Stage Application of PCT/JP04/09600, filed on 30 June 2004 and claims priority to Japanese Application No. 2003-430615, filed on 25 December 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 26 October 2009 was filed after the mailing date of the First Action on the Merits on 18 August 2009. The submission complies with the provisions of 37 CFR 1.97(c). Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following rejection is new.

Claims 3-5 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3, 4, and 14 recited the phrase "based on an entered fluorescence intensity data". The metes and bounds of the claim are rendered indefinite by the phrase. The phrase make the claim unclear with respect to the measured fluorescense data and the determination elution. As recited in the instant claims the elution volume appears to be determined from a fluorescence intensity that is distinct from the intensity that is measured by the detection means. This rejection could be overcome by amendment of the phrase "based on an entered fluorescence data" to "from the fluorescence data". Claim 5 is also rejected because it depends from claim 3, and thus contain the above issues due to said dependence.

Claims 3, 4, and 14 are unclear with respect to the term "based on". The metes and bounds of the claim are rendered indefinite by the lack of clarity. The usage of the term in the claims does not provide a measure the meaning of based on. This rejection could be overcome by amendment of the term "based on" in the claims to more definite language, if the amendment does not introduce new matter.

The following rejection is new.

As set forth below, claims 3-5 invoke 35 USC 112, Sixth Paragraph. The MPEP2181 (II) states, "If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc). In the instant case, the specification does not provide an adequate disclosure showing the structure, material or acts for these "means-plus-function" limitations, for reasons as set forth below.

Therefore, applicant fails to particularly point out and distinctly claim the invention as required by the second paragraph of 35 USC 112, and one skilled in the art would not know what are meant by these "means-plus-function" limitations, and the metes and bounds of the claimed invention are thus unclear.

First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claim 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3-5 are directed to a system for analyzing sugar chain structure. First, claims 3-5 recite limitations using the phrase "means for". Second, in claims 3-5 the recited limitation modifies the phrase "means for" with functional language. For example, line 5 recites, "a detection means which...detects". Finally, the "means for" phrases of claims 3-5 are not modified by sufficient structure, material, or act for achieving the functions of claims 3-5. Based on the previous three conditions in claims 3-5, the limitations of claims 3-5 are considered to invoke 35 USC 112, Sixth paragraph as set forth in MPEP 2181.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus-function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language." In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

In the instant case, the specification fails to set forth an adequate disclosure of what is meant by "a storage means", "a display means", "means for taking a data combination" and "a detection means" as recited in claim 3.

Claims 3-5 are indefinite because the metes and bounds of the claimed means have not been pointed out particularly in the disclosure. The disclosure fails to show, for example, a "storage means". At p. 21, lines 4-15 and referring to figure 4, the specification provides the example of a composition of a computer system comprising three means for storage. The storage means appear to be distinct entities. However, the

description fails to describe how one of ordinary skill would identify the appropriate structures each storage means. The description does not set for the material or structure for the means as recited in claims 3-5. Thus, one of skill in the art would be reasonably doubt that the inventor, at the time the application was filed, had possession of the claimed invention.

Response to Arguments

The rejection of claims 9-11 as indefinite under 35 USC 112, Second paragraph and lacking written description under 35 USC 112, First paragraph with respect to limitations interpreted as invoking 35 USC 112, Sixth paragraph is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is newly applied.

Claims 1-6, 8, 9, and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al. (Reference CE, IDS filed on 2 February 2007) in view of Chan et al. (Combinatorial Chemistry & High Throughput Screening, Vol. 5, No. 5, p. 395-406, 2002) and in view of Nilsson et al.

The claims are directed to a method and system of analyzing saccharides in which a labeled oligosaccharide is introduced to a Frontal Affinity Column (FAC) with parallel columns, the interaction between the saccharide chain and the columns is measured and the pattern of binding is compared to a known binding pattern

Hirabayashi et al. shows a method and apparatus for the analysis of oligosaccharides in which fluorescently labeled oligosaccharides are contacted with protein immobilized on a solid surface. Hirabayashi et al. shows the solid surface is a FAC column (p. 237, col. 1). Hirabayashi et al. shows a system comprising a storage means, a detection means, a calculation means, and a display means (figure 3).

Hirabayashi et al. shows the interaction between the labeled oligosaccharides and the column is measured (p. 238, col. 1). Hirabayashi et al. shows that oligosaccharidebinding proteins prefer particular oligosaccharides (p. 250, col. 1). In Figure 4, Hirabayashi et al. shows binding profiles for a plurality of known oligosaccharides of figure 2 for a plurality of oligosaccharide-binding proteins or carbohydrate recognition domains (CRDs). Figure 4 shows oligosaccharide structure is determined by comparison of oligosaccharide-binding proteins binding patterns. With respect to claims 2, 5, 8, and 11, Hirabayashi et al. shows the immobilized proteins are lectins (p. 235, col. 2). With respect to claims 4 and 14, Hirabayashi et al. shows the calculation of elution volume of oligosaccharides differences to a control elution volume to determine an affinity constant (p. 237, col. 2-p. 238, col. 1). Hiarabayashi et al. shows the values are compared to a database (table3) (p. 238, col. 2).

Hirabayashi et al. does not show a FAC system with parallel columns.

Chan et al. shows a FAC system having parallel columns (abstract). Chan et al. shows the parallel column system provides the advantage of improving the ability to handle large compound collections in a high-throughput analysis (p. 403, col. 2).

Nilsson provides a discussion of lectins and their binding of oligosaccharides.

Nilsson shows lectins are proteins that recognize and bind to specific carbohydrate structural epitopes (p. 349, col. 2). Nilsson shows that lectins recognize different sugar structures, make lectins invaluable biochemical tools (p.350, col. 1). Nilsson shows using microarray techniques binding partners can be made by either linking the protein or the carbohydrate to a solid surface (p. 351, col. 1). Nilsson shows that the pattern of

lectin binding to oligosaccharides can be determined using microarrays and FAC (p. 351, col. 1). Thus, the structural organization of the saccharide constituents is determined.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method and system of Hirabayashi et al. with the parallel column FAC system of Chan et al, because Chan et al. shows the parallel column system provides the advantage of improving the ability to handle large compound collections in a high-throughput analysis. It would have been further obvious to modify the Fac system of Hirabayashi et al. and Chan et al. using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson because Nilsson shows the ability of lectins to recognize different sugar structures makes lectins in valuable biochemical tools.

The following rejection is reiterated from the previous action.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (WO 02/083918) in view of Nilsson (Analytical Chemistry, Volume 75, Issue 15, p.348-353, 01 August 2003) and in view of Joos et al. (Current Opinion in Chemical Biology, 2001, Vol. 6, p.76-80).

Claim 6 is direct to a method of analyzing oligosaccharides in which a fluorescently labeled oligosaccharide sample contacts a solid support comprising a plurality of proteins and detecting the pattern of protein-oligosaccharide binding without

washing. In the embodiment of claim 7, the excitation light is an evanescent wave. In the embodiment of claim 8, the protein is a lectin.

Wang shows method of detecting the binding of an agent to a microarray (p. 28). Wang shows, as in the embodiment of claim 8, lectins, or antibodies are immobilized on the microarray (p. 28). Wang defines agents to be glycomers or oligosaccharides (p. 22 and p. 23). Wang shows the determination of binding is made by detecting fluorescence (p. 29).

Wang et al. does not explicitly show determining a pattern of oligosaccharide binding to lectin to analyze structure or detecting without washing.

Nilsson provides a discussion of lectins and their binding of oligosaccharides. Nilsson shows lectins are proteins that recognize and bind to specific carbohydrate structural epitopes (p. 349, col. 2). Nilsson shows that lectins recognize different sugar structures, make lectins invaluable biochemical tools (p.350, col. 1). Nilsson shows using microarray techniques binding partners can be made by either linking the protein or the carbohydrate to a solid surface (p. 351, col. 1). Nilsson shows that the pattern of lectin binding to oligosaccharides can be determined using microarrays (p. 351, col. 1). Thus, the structural organization of the saccharide constituents is determined.

Joos et al. shows that the sensitivity of protein arrays can be increased by excitation of fluorophores with evanescent waves (p. 78, col. 1). The use of evanescent waves also allows performing microarray binding detection without washing steps (p. 78, col. 1). Joos et al. shows that (p. 78, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson because Nilsson shows the ability of lectins to recognize different sugar structures makes lectins in valuable biochemical tools. It would have been further obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang for the detection of oligo saccharide agents using lectins immobilized on a substrate to analyze oligosaccharide structure as suggested by Nilsson with detection using evanescent waves of Joos et al. because Joos et al. shows evanescent waves have the advantage of providing signals that are a hundred times higher than conventional excitation.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues lectin/sugar binding specificity was unknown to those of ordinary skill in the art at the time of invention. The argument is not persuasive. Nilsson shows that lectins were well known at the time of invention to possess distinct oligosaccharide binding capabilities. For example, Nilsson shows the use of lectins as biochemical tools to elucidate the chemical structure of the ABH histoblood group antigens, the system that is based on the structural differences in terminal saccharides in human glycolipids and glycoproteins in the 1950's (p. 349, col. 2-p. 350, col. 1). Applicant argues the one would not have been motivated to immobilize proteins that interact with sugar chains to analyze sugar chains. The argument is not persuasive.

Nilsson shows that during 2002 three reports were published that detailed large scale methods to study protein carbohydrate interaction by microarray techniques which are based on the finding the binding partners can be made by either linking the protein or the carbohydrate to a solid substrate (p. 350, col. 2-p. 351, col. 1). Applicant argues that that one would have not been motivated by Nilsson to modify the method of Wang to use lectins. The argument is not persuasive. Nilsson shows that at least three independent research groups successfully developed methodologies to probe proteinsaccharide interactions. Applicant cites p. 350, column 2 of Nilsson that states, "The area presents special analytical challenges because of the weak nature of the biomolecular interactions and the solubility differences between carbohydrates, which are extremely hydrophilic, and proteins, which have a wide range of hydrophobicities". However, Nilsson qualifies the previous statement at p. 350, col. 2, para. 3, last three lines, "The low affinity of lectins for carbohydrates is, to some extent, compensated for by their multivalency, which increases the avidity of the binding." With respect to applicants argument that a person at the time of invention would not have able to distinguish the structures of sugar chains without the detailed explanation found in applicants specification is not persuasive. As indicated above Nilsson shows that lectins and saccharide binding proteins have been used successfully since the 1950's to elucidate saccharide structures. The rejection is maintained.

The following rejection is reiterated from the previous action.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above, and further in view of and Shalon et al. (Genome Res., Vol. 6, p. 639-645, 1996) in view of Pawlak et al. (Proteomics 2002, 2, 383-393).

Claim 9 is directed to a system comprising a storage means; a detection means; a calculating means, and a displaying means that implements a method of analyzing sugar chains.

Wang in view of Nilsson in view of Joos et al. as applied to claims 6-8 above shows a method of analyzing sugar chains using evanescent waves.

Wang in view of Nilsson in view of Joos et al. does not explicitly show a system Shalon et al. shows a microarray system comprising a storage means; a detection means; a calculating means, and a displaying means (p. 644, col. 2).

Pawlak et al. shows a microarray system adapted with a specialized detection means to detect signals from microarray substrates that rely on evanescent waves (p. 385, col. 1). Pawlak et al. shows that the differences between the evanescent wave and conventional excitation, such as that performed in Shalon et al., is approximately an 80-fold increase in signal to noise (figure 1). Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during microarray hybridization that is especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided (p393, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Wang in view of Nilsson in view of Joos et al. as

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applied to claims 6-8 above to perform the method with the system of Shalon et al. because all the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention. It would have been further obvious to modify the detection means of Shalon et al. with the detection means of Pawlak et al. because Pawlak et al. shows the evanescent wave excitation allows one to omit washing steps during microarray hybridization which is especially beneficial for weak affinity reactions as a dissociation of weak complexes during washing can be avoided.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that Shalon et al. and Pawlak do not cure the deficiencies of Wang et al., Nilsson, and Joos et al. The argument is not persuasive because Wang et al., Nilsson, and Joos et al. are not deficient for the reasons provided above. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following rejection is reiterated from the previous action.

Claims 6-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, and 12 of copending Application No. 10/596692. Although the conflicting claims are not identical, they are not patentably distinct from each other. The method as in claim 6 of the instant application is directed to a method in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction. Similarly, in claim 1 of copending Application No. 10/596,692, a method is claimed in which a fluorescent oligosaccharide is contacted with a substrate comprising immobilized protein and measuring the interaction.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that a terminal disclaimer will be filed upon indication of allowable subject. The provisional rejection is maintained.

The following rejection is reiterated from the previous action.

Claims 9-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 11/917,921. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 9-11 of the instant application are directed to an apparatus or system comprising a storage means, detection means, calculation means, and a display means in which evanescent waves are used to excite fluorophores and lectins are immobilized on a substrate. Similarly, claims 1-9 of copending Application No. 11/917,921 are also directed to an apparatus comprising storage means, a measuring or detecting means, and a calculation means. Although claims 1-9 of copending Application No. 11/917,921 does not show a display means, it would be obvious to one of ordinary skill in the art to modify the apparatus of copending Application No. 11/917,921 to include a display means. Such a modification would advantageously provide results of the apparatus function to the user.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 18 November 2009 have been fully considered but they are not persuasive. Applicant argues that a terminal disclaimer will be filed upon indication of allowable subject. The provisional rejection is maintained.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARLHEINZ R SKOWRONEK/ Primary Examiner, Art Unit 1631

12 May 2010